4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0928]

Draft Guidance for Industry on Recommendations for Preparation and Submission of Animal

Food Additive Petitions; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice published in the <u>Federal Register</u> of Wednesday, September 11, 2013 (78 FR 55727), announcing the availability of the draft guidance for industry (GFI #221) entitled

"Recommendations for Preparation and Submission of Animal Food Additive Petitions."

DATES: Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sharon Benz, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6864, sharon.benz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

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In the Federal Register of Wednesday, September 11, 2013 (78 FR 55727), FDA

announced the availability of a draft guidance for industry (GFI #221) entitled

"Recommendations for Preparation and Submission of Animal Food Additive Petitions."

Interested persons were originally given until November 12, 2013, to comment on the

draft guidance.

II. Request for Comments

FDA is reopening the comment period due to the inability of some commenters to submit

comments through the http://www.regulations.gov Web site from November 4, 2013, through

November 13, 2013, because of technical difficulties at that Web site.

III. How to Submit Comments

Interested persons may submit either electronic comments regarding this document to

http://www.regulations.gov or written comments to the Division of Dockets Management (see

ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through

Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: December 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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